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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/714,987	09/17/1996	HUGH SHARKEY	17616-705	4099
23715	7590	01/10/2008		
JOEL R. PETROW SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116				
EXAMINER				
SHAY, DAVID M				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
01/10/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

08/714,987

Applicant(s)

SHARKEY ET AL.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 25, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-93 and 95-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-93 and 95-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/C2)
Paper No(s)/Mail Date October 25, 2007
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2007 has been entered.

Applicant argues that the examiner has not provided a *prima facie* case of obviousness because the examiner has not addressed all the recitations of claims 90 and 93, i.e. "sensing an elevated composite temperature"; "delivering sufficient energy...causes fluid medium...to increase in thermal energy."; "moving the energy delivery device away...after delivering sufficient energy."; and "moving the delivery device back...and sensing an elevated composite temperature due to the increased thermal energy in the fluid medium" (emphasis in original). However, this is not the case. Applicant must agree that 'Kirwin is particularly focused on a method for reducing the size of a "greatly hypertrophied prostate by withdrawing fluid and coagulating albumen"' (see the instant response, page 9, second sentence of the third full paragraph). Clearly, for fluid to be withdrawn, it must first be present. As neither Kirwin nor applicant has proposed a mechanism by which the heating of the fluid is avoided, the examiner has no choice but to presume that the ordinary laws of thermodynamics and physics are operative and that the fluid already present is also heated by the applied RF energy in the method of Kerwin. However, even assuming, *arguendo*, that somehow the fluid already present due to its composition, for example, were not heated, the water used for irrigation (see pages 485-486) would clearly be heated thereby. As has already been determined by the Board Of Patent Appeals and Interferences, in the decision rendered March 15, 2006, the sensing of composite

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temperature is an inherent property of the use of a device with a temperature sensor on the surface of tissue in the presence of a fluid medium (see the decision rendered March 15, 2006, pages 7-8 thereof). Given the intrinsic nature of this, any thermal feedback in this context, as described in Swanson et al ('184) would also inherently provide this step. Thus applicant's arguments are not convincing.

Claims 90-93 and 95-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirwin in combination with Swanson et al ('184). Kirwin teaches a method of tissue shrinkage, but does not teach measuring temperature. Swanson et al ('184) provide the teaching the desirability of determining the temperature of tissue to which energy is applied. It would have been obvious to the artisan of ordinary skill to provide the temperature detector configurations and methods of Swanson et al in the method of Kirwin, since this would allow the temperature to be maintained in the desired range more easily, which control will necessarily affect the depth to which the shrinkage effect occurs, or to employ the shrinkage method of Kirwin in the method of Swanson et al, since this would destroy the electrical functionality of the tissue, without removing it, or compromising its stability-inducing structural integrity, and in either case, to move the device away from the site and return it thereto, since this is well within the scope of one having ordinary skill in the art; is not critical; provides no unexpected result; and since the removal would allow the prostate or cardiac shrinkage to be determined, so as to determine whether or not the shrinkage was sufficient, and the replacement would allow for further shrinkage, should it be deemed necessary by the physician, thus producing a method such as claimed.

Claims 101-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirwin in combination with Swanson et al ('184) as applied to claims 90-93 and 95-100 above, and further in view of Sand ('709). Sand ('709) teaches a method of tissue shrinkage, noting that collagen is the compound responsible for the shrinkage, and also noting that collagen is contained in ligaments and tendons, and also that the shrinkage can be used to treat musculoskeletal injuries, Sand also notes that the controlling parameter for the shrinkage is temperature. It would have been obvious to the artisan of ordinary skill to employ the tendon and ligament shrinkage method of Sand in the combined methods of Swanson et al and Kirwin, since this would allow the treatment of musculoskeletal injuries, such as injuries to the knee and ankle, which would otherwise require grafts to achieve similar results, or to employ the RF based shrinkage method of Kirwin in the method of Sand, since Sand explicitly teaches that the controlling parameter for shrinkage is the temperature of the tissue, rather than any particular energy used to produce the temperature change, and to employ the temperature sensor of Swanson et al, for the same reason, thus producing a method such as claimed.

Applicant's arguments filed May 11, 2007 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and

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Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER